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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

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TITLE OF THE INVENTION (500 characters max)

OPTHALMIC MICROSURGICAL INSTRUMENTS

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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
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Respectfully submitted,

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Provisional Patent Application

Ophthalmic Microsurgical Instruments

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Assigned to: iScience Surgical Corporation

Incorporation by Reference:

1 Co-pending PCT application number PCT/US03/08866 is hereby incorporated by reference in its entirety.

Background of Invention:

2 Glaucoma is a disease condition of the eye in which increased intraocular pressure (IOP) is created by blockage of the drainage mechanism for the aqueous fluid produced in the anterior portion of the eye. Such conditions are usually treated by topical drugs in the form of eye drops, but may result in surgical treatment if drug treatment becomes ineffective or if patient compliance is an issue. Traditional glaucoma surgery such as trabeculectomy, involves a flap dissection of the eye and the removal of a portion of the trabecular meshwork (TM). The aqueous fluid is directed posteriorly under the surgical flap and to a sub-conjunctival lake known as a bleb. Post-surgical complications and bleb management are significant issues with trabeculectomy and similar procedures. Furthermore, the control of the aqueous outflow is achieved through the management of the integrity of the surgical flap rather than controlling the opening in the TM. Other procedures involving laser energy to create holes in the TM are partially successful however long term results are limited as compared to trabeculectomy.

3 Recently developed surgical treatments for glaucoma involve surgically accessing Schlemm's Canal by manner of a surgical flap or flaps and subsequently dilating or expanding the canal to increase aqueous humor drainage in the natural drainage pathway. Current procedures and instruments can only access a short passage of Schlemm's Canal from either side of the surgical site. Stegmann, et al. in US 5,486,165 discloses a microcannula designed for delivery of substances to Schlemm's Canal during such a procedure. In EP 0898947A2, Grieshaber, et al. disclose an improvement to the Stegmann apparatus to deliver substances or stents for maintaining the passage of fluid in the canal. Other inventions disclose the use of microcatheters to introduce water-jet type cutting apparatus or bladed mechanisms to the canal for disruption of

the TM. However these methods cut the TM network open in a non-controlled manner and do not remove tissue or debris from the operative field.

4 The treatment of glaucoma usually involves patient specific requirements for the amount of drainage increase desired by the physician. It is therefore of advantage to be able to remove a controlled amount of the TM or juxtacanicular tissues in order to be able to titrate drainage rates and control the disease process on a patient specific basis. Furthermore, it is desired to perform the controlled removal of tissues from within Schlemm's Canal in order to facilitate the return to natural drainage patterns without the requirement for blebs and the concomitant complications, and to enable less invasive surgical methods. It is also advantageous to physically stabilize the tissues in order to facilitate control of the amount of tissues being removed.

5 This invention is directed at ophthalmic microsurgical instruments which may be directly inserted into Schlemm's Canal to allow controlled removal of trabecular meshwork tissues to effect the reduction of intra-ocular pressure. It is a further object of this invention to describe an instrument which allows the directed access to a tissue space such as Schlemm's Canal for a curved microcannula. The instrument is useful in allowing controlled guidance by the surgeon while viewing through the surgical microscope or by non-invasive medical imaging.

Known prior art:

United States Patent 4,501,274
Skjaerpe February 26, 1985
Microsurgical instrument

United States Patent 5,486,165
Stegmann January 23, 1996
Method and appliance for maintaining the natural intraocular pressure

United States Patent 6,142,990
Burk November 7, 2000
Medical apparatus, especially for reducing intraocular pressure

United States Patent 6,221,078
Bylsma April 24, 2001
Surgical implantation apparatus

United States Patent 6,283,940
Mulholland September 4, 2001
Catheter

United States Patent 6,375,642 B1
Grieshaber , et al. April 23, 2002
Method of and device for improving a drainage of aqueous humor within the eye

United States Patent 6,494,857 B1
Neuhann December 17, 2002
Device for improving in a targeted manner and/or permanently ensuring the ability of the aqueous humor to pass through the trabecular meshwork

United States Patent Application 20020013546
Grieshaber, Hans R. ; et al. January 31, 2002
Method and device to improve aqueous humor drainage in an eye

United States Patent Application 20020111608
Baerveldt, George ; et al. August 15, 2002
Minimally invasive glaucoma surgical instrument and method

United States Patent Application 20020082591
Haefliger, Eduard June 27, 2002
Device for the treatment of glaucoma

United States Patent Application 2003014092
Inventor(s): Neuhann Thomas (De)
Apparatus for the treatment of glaucoma

Patent Number: EP0898947 A2
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: EP1114627 A1
Inventor(s): Grieshaber Hans R (Ch); Stegmann Robert Prof M D (Za)
Method and apparatus to improve the outflow of the aqueous humor of an eye

Patent Number: WO0064389
Inventor(s): Brown Reay H (Us); Lynch Mary G (Us); King Spencer B Iii (Us)
Trabeculotomy device and method for treating glaucoma

Patent Number: WO02056805
Inventor(s): Roy Chuck; Baerveldt George
Minimally invasive glaucoma surgical instrument and method

Patent Number: WO02074052
Inventor(s): Smedley Gregory T; Gharib Morteza; Tu Hosheng
Applicator and methods for placing a trabecular shunt for glaucoma treatment

Description of Invention:

6 The ophthalmic microsurgical instruments comprise a thin walled outer sheath microcannula with a connector at the proximal end, a communicating channel between and a distal tip, as shown in Figure 1. An inner member which fits and slides within the sheath may be incorporated, the inner member comprising at least a proximal end and a distal tip. The distal end of the instrument is preferably curved in a manner to approximate the diameter of Schlemm's Canal. The instrument may also comprise a guidance means to effect proper advancement of the curved distal portion. Furthermore the instrument may comprise means to mechanically stabilize the target tissues. The tissues may be held in tension or compression for controlled removal of tissue.

7 The microcannula may be introduced into Schlemm's Canal manually or as part of a system to provide surgical support or guidance. Once inserted into a tissue tract such as Schlemm's Canal, the microcannula may be progressively advanced to the appropriate areas for treatment. The distal end is preferably sized and curved to target at least one half the length of the Canal. Treatment of the entire Canal may be effected by inserting the instrument in the opposite direction from the first treatment at the access point to Schlemm's Canal. The positioning of the instrument in Schlemm's Canal can be verified by several means including a fiber-optic beacon tip inner member, a change in pressure/vacuum resistance in the surrounding environment as the system enters the Canal, a change in tissue color of the tissues of the Canal, direct visual location during surgical cut-down or by external image guidance such as ultrasound or optical coherence tomography. Accurate positioning within the Canal can be aided by features of the instrument.

8 The controlled removal of TM tissues may be accomplished by various means. The outer sheath may be configured to allow for tissue removal separately or in conjunction with an inner member. Alternatively, the outer sheath may be utilized to maintain a tract to the operative site to allow an inner member instrument to perform the tissue cutting. The sheath also functions to provide a disposal path for the excised tissues and surgical debris. A suction or vacuum device may be incorporated to clear the operative field and the cannula lumen. Furthermore the ability of the cannula to remove particles and debris may be used by itself or in conjunction with other cutting methods such as laser trabeculoplasty in order to enhance the outcome by removal of waste particles.

9 The microcannula may comprise a thin walled polymer or metallic tube **1** of sufficient stiffness to allow it to be advanced into tissues or along a tissue tract such as Schlemm's Canal, and of sufficient flexibility to follow the radial tract of Schlemm's Canal. The proximal connector **2** may be of a Luer type or similar system for the attachment or introduction of secondary elements or may be designed for attachment only to specific components. Due to the small size of Schlemm's Canal, approximately 200 microns in diameter, the microcannula system must be appropriately sized. Typically, the microcannula is sized in the range of 100-300 microns outer diameter with a wall thickness from 10-100 microns. Due to the curvature of a tissue space such as Schlemm's Canal, the microcannula may be flexible in the appropriate dimensions. In some embodiments, a predetermined curvature **3** may be applied to the inner member and/or the outer sheath during fabrication. The curvature is preferably slightly greater than the curvature of Schlemm's Canal in order to prevent the instrument from prematurely rupturing the TM or juxtacanicular tissues while advancing the microcannula. It is also desirable for a portion of the instrument to be able to be swiveled at least 180° around to provide for handedness to the curved microcannula. This allows the surgeon to cannulate the entire circumference of Schlemm's Canal from a comfortable working position.

10 Suitable materials for the microcannula include metallic films, polyetheretherketone (PEEK), polyimide, polyamide, polysulfone, or similar materials. The sheath may also comprise surface treatments such as lubricious coatings to assist in tissue penetration and ultrasound or light interactive coatings to aid in location and guidance. The microcannula may also have markings **4** on the exterior for assessment of depth in the tissue tract or Schlemm's Canal. The external markings allow user assessment of the length of the tissue tract or Schlemm's Canal accessed by the microcannula, and the approximate location of the microcannula tip.

11 The microcannula **5** may also comprise a segment or series of segments capable of being expanded in a radial direction in order to place tension on the target tissues, as shown in Figure

2. The segments may comprise means such as stent-like structures, micro-balloons or elastomeric sections **6** which may be inflated or deformed in a radial manner **7**. Multiple expandable segments may be used to stabilize and isolate segments of Schlemm's Canal for surgical or drug treatment through the microcannula lumen. Furthermore, the expandable segments may be slidably disposed about the central axis such that the segments may be translated axially apart from each other to provide further tension on the tissues. The expandable segments may comprise polymers and elastomers such as latex, silicone rubber, urethane, vinyl, Pebax or may be a metallic structure comprised of shape-memory or superelastic alloy, stainless steel, tungsten or similar. Alternatively, another outer member may be disposed about the microcannula as a tissue stabilization means.

12 Depending on the application, the inner member may be used to guide the positioning of the microcannula, provide fluid access, or guide surgical tools and instrumentation. The inner member may comprise a guide wire, hollow needle or tube, micro-trocar or similar element and comprises a proximal end and a distal tip, and may contain a communicating channel between. The inner member may also comprise sensing means such as a pressure transducer, light pipe or fiber optic to aid in determining location, local fluid pressure, blood flow or other parameters. The inner element is sized correspondingly to fit slidably within the microcannula and therefore will be in the range of 90-240 microns in outer diameter. If hollow, the inner diameter will be in the range of 40-210 microns. The inner member may be removed during the procedure and replaced sequentially with instruments or tools.

13 A first inner member used for initial placement preferably comprises a signaling beacon to identify the location of the microcannula tip relative to the target tissues, as shown in Figure 3. The beacon may comprise an echogenic material for ultrasound guidance, an optically active material for optical guidance or a light source for visual guidance. In one embodiment, a plastic optical fiber (POF) **8** is used to provide a bright visual light source at its distal tip **9**. The distal tip of the POF is positioned at or slightly beyond **10** the end of the microcannula sheath **11** and the emitted signal may be detected through the scleral tissues visually or using such sensing means such as infrared imaging. The POF may also comprise a tip which is beveled or mirrored or otherwise configured to provide for a directional beacon. If the emitted directional light is directed at the TM, the surgeon may view the illuminated spot in the anterior angle using a goniometer lens, and verify placement of the operative instrument at the targeted tissues. The beacon may be illuminated by a laser, laser diode or light-emitting diode **12**, and preferably is powered by batteries **13** and is a sterile disposable component of the instrument set. Upon arrival at the target tissues, the beacon assembly and POF may be removed. The connection point may be

sealed with a cap or preferably with a self-sealing mechanism such as a one-way valve or an elastomer seal.

14 In one embodiment, the instrument set also comprises a fitting as the connection point for the illumination package. Additionally, as shown in Figure 4, the instrument may contain a central section **14** comprising a single or multiple side fittings **15** to allow the attachment of ancillary equipment such as syringes, vacuum or pressures sources, sensing means and the like. The attachment fittings may comprise standard designs such as Luer fittings or may be designed to only accept connection with specific components.

15 It is also desired to provide a means for the surgeon to easily guide a curved cannula into Schlemm's Canal without prematurely piercing the TM, puncturing the iris or creating a false tract into the scleral tissues. Traditionally in the field of vascular access, a hollow sheath or introducer is placed into the target vessel and then operative catheters are passed through the introducer. This allows the straightening and placement of curved catheters or surgical instruments. However, due to their size, structures like Schlemm's Canal do not lend themselves to such use of an indwelling introducer.

16 Therefore a design for a guidance means which allows for the straightening of the curved microcannula and maintains the stability and guidance of the instrument as it is advanced in Schlemm's Canal is herein described. In one embodiment shown in Figure 5, the guidance means comprises a hollow shaft **16** of sufficient stiffness to prevent bending while being advanced and manipulated by the surgeon. Within this shaft resides means **17** of holding the microcannula **18** and other members as required. Slidably disposed about the distal portion of the shaft is a hollow guide tube **19** constructed such that its travel along the shaft is a fixed distance. The distal tip of this guide tube **20** is sized to allow passage of the microcannula and surgical instruments. When the guide tube is slid along the axis of the shaft to its most distal position, the end of the microcannula resides a small measured distance **21** beyond the tip of the guide tube and the curvature is effectively straightened **22**.

17 The guide tube distal tip **20** can then be directed at the ostium of Schlemm's Canal and the guide tube held in place. The guide tube may have a handle disposed at approximately right angles to the tube in order to facilitate manual stability without having the surgeon's fingertips obscuring the operative field. The handle may be permanently attached or it may be removable after placement of the guide tube. The guide tube is held in position and the shaft and instrument assembly are then advanced **23**, as shown in Figure 6, allowing the curved microcannula **24** to enter the Canal

without the need for the surgeon to move his hands from the most stable and comfortable operative position. The guidance means and handle may comprise metal or plastic components.

18 The operative function of the invention is an instrument to cut and/or remove tissues from the trabecular meshwork (trabeculectomy) in such a manner that the size of the subsequent void in the TM is controlled and repeatable. In some applications the instrument may be used to remove a controlled layer of adjacent target tissue, such as the external layer of the TM. Furthermore, the procedure can be performed at multiple sites within the eye to effect treatment per the patient's requirements by using the microcannula sheath for repositioning to other target locations from within Schlemm's Canal.

19 In one embodiment the microcannula **25** alone is used to remove portions of the TM using suction means **26**, as shown in Figure 7. The microcannula is advanced into Schlemm's Canal **27**. A vacuum syringe, vacuum or aspiration pump is used to provide suction and a portion of the TM is pulled into the lumen **28** and removed. Control of the suction characteristics may be used to control the amount of tissue removed.

20 In another embodiment shown in Figure 8, the distal tip of the microcannula **34** is closed off **29**. A hole or series of holes **30** are disposed along the inner wall **31** of the cannula, directed toward the TM. Suction is applied **32** to pull a small amount of TM tissue into the lumen and apply tension to the target tissue. An inner member **33** comprised of a thin hollow shaft is then extended through the microcannula **34** and may be rotated, to cut off the intruding tissues. The excised tissue may be removed by a suction mechanism through the lumen. The amount of tissue removal may be controlled through the sizing of the ingress holes and the amount of suction applied. The outermost layer of the TM interfacing Schlemm's Canal may be removed by minimal application of suction, or alternatively openings through the TM of controlled geometry may be formed with greater amounts of suction.

21 Furthermore, the microcannula may contain stabilization means in conjunction with cutting means. The microcannula may comprise a multilumen tube such that each lumen is connected separately to a hole or a series of holes along the inside radius facing the target tissues. For example, a two-lumen microcannula may be constructed comprised of three holes a set distance apart along the inner radius. The outermost two holes are connected to one lumen of the microcannula and the central hole to the second lumen. In this manner, a low suction pressure may be applied to the outermost holes, providing tissue stabilizing forces, while a higher suction pressure may be applied to the center hole, removing a controlled portion of tissue.

22 In a similar embodiment shown in Figure 9, the microcannula lumen is open **35** and a rotating hollow inner member **36** is employed. The distal tip of the inner member may be beveled or sharpened and is extended just slightly beyond the end of the cannula **37**. Suction is applied to the cannula and the inner member is rotated **38** to provide a cutting action. As the instrument is advanced, the fragile TM tissues will be pulled into the Canal **39** allowing the inner member to cut away portions as required. The amount of tissue removal is controlled by extent of advancement during the cutting process.

23 In another embodiment shown in Figures 10a, 10b, the distal tip of the microcannula **40** is further curved or bent at an angle such that the tip will penetrate the TM. An inner member **41** of sufficient stiffness to straighten the tip **42** is used during placement. When the inner member is retracted enough, the tip will revert to its curved state **43** and penetrate the TM tissues creating a tear of controllable size. Conversely, the inner member may be bent or curved at an appropriate dimension and the outer sheath is of sufficient stiffness to straighten the tip for introduction. At the appropriate target the inner member is extended beyond the cannula or the cannula is retracted to allow the tip to penetrate the TM. Furthermore, in each of these embodiments the retraction or advancement of the instrument will allow for disruption of TM tissues along a line. Suction may be applied to the instrument to remove tissue debris.

24 In another embodiment shown in Figure 11, the instrument distal end is comprised of two concentric thin-walled tubes. The outer tube **44** contains a cut-out or window **45** near the distal end and aligned along the side of the tube **46** which interfaces the TM. The inner tube **47** contains an angled slit **48** partially through the tube which creates a sharp pointed flap **49** directed proximally and also aligned with the window in the outer tube and the TM. The flap **49** is pre-bent to allow it to project inward from the tubing **47**, in the direction of the TM and is used as a piercing and cutting member. The outer tube **44** is slidably disposed about the inner tube. During insertion into Schlemm's Canal, the outer tube is positioned such that the window is not adjacent to the flap and the flap is thereby constrained within the outer tube. At the operative target position, the outer tube is advanced so that the window is over the flap, allowing the flap to protrude from the assembly. The instrument is retracted slightly allowing the flap to pierce the TM and then retracted a specified amount such that the full length of the flap has pierced the tissues. The outer tube is then retracted, moving the window proximally, causing the flap to be pulled back and thereby cutting a portion of the TM approximating the geometry of the flap and constraining the excised tissue within the inner tube for disposal. Suction may be used to remove the tissue from the lumen and the procedure repeated as required.

25 In another embodiment, the instrument distal end comprises an inflatable member with at least one cutting element disposed on the surface interfacing the TM. After positioning of the microcannula to the appropriate location in Schlemm's Canal, the deflated member is inserted into the lumen of the microcannula and positioned at the distal tip. Rotational positioning of the cutting element toward the TM is assisted by the mechanical interface of the microcannula and the inner member. The inner member is inflated with gas or fluid through a tubular channel and connector on the proximal portion of the instrument. Expansion of the inflatable member with a syringe expands the tip and pushes the cutting member into the target tissue while providing tensioning of the tissues. Multiple cutting elements may be used to effectively remove a section of tissue of controlled geometry. Suction may also be incorporated to remove tissue debris through the microcannula lumen. The tip may be deflated to allow retraction into the microcannula for repositioning or interchange with another inner member component.

26 The microcannula may also comprise further means to stabilize the target site for controlled removal of tissues. An inflatable or expandable section or sections along the outer surface of the microcannula may be used to stabilize an area. Balloons or hydraulically expandable polymeric segments may be inflated/expanded in situ to place the tissues under tension. Expandable segments may comprise elastomers such as silicone rubber, latex, urethane, and vinyl. Alternatively, the expandable segments may comprise a basket or series of struts or stent-like structures fabricated from superelastic or shape memory materials such as Nitinol. The expandable structure would be activated or mechanically released to expand during the procedure and then retracted or compressed for removal.

27 The microcannula may also be used to deliver a fiber optic for laser ablation of the tissues from within Schlemm's Canal. The instrument may then be used to remove the ablative residue and any tissue debris from the site and deliver adjuvants or medications to prevent excess fibrosis during wound healing.

Examples:

Example 1:

28 A microcannula system was fabricated for experimentation on ex-vivo human eyes obtained from an eye bank. The microcannula consisted of a 30 gauge tubing adapter (Small Parts, Inc.) with a distal tip comprised of polyimide tubing bonded into the lumen of the tube adapter. The tube adapter was a standard hypodermic needle, cut to ½" (12.5 mm) length with a perpendicular (straight) cut distal end and a female Luer at the proximal end. The tube adapter had an inner diameter of 150 microns and an outer diameter of 300 microns. A section of polyimide tubing

(MicroLumen, Inc.) with inner diameter of 110 microns and a wall thickness of 14 microns was bonded into the distal tip of the tube adapter with cyanoacrylate adhesive and allowed to cure overnight. Assemblies were fabricated with 1.0 and 1.5 cm of polyimide tubing extending from the tube adapter. A 2 cm section of section of stainless steel wire (Fort Wayne Metals) 102 microns diameter was mounted onto a Luer cap for attachment to the Luer connector of the microcannula. The wire tips were hand ground to a spade type point and a tapered cone type point. In some assemblies, the stainless wires were bent by hand into a curve of approximately 14 mm radius, to facilitate advancement along the curvature of Schlemm's Canal.

29 Ex-vivo human eyes were used to perform experiments with the microcannulae. The human eyes were placed under a stereomicroscope. Using ophthalmic scalpels, successive layers of the sclera were cut away until Schlemm's Canal was located. Various examples of the microcannula system were successfully guided into the Canal. When the tip of the microcannula was into the ostium of the Canal approximately 1-2 mm, the inner member was removed. The microcannulae were advanced to determine their ability to track the Canal. In all cases the microcannulae were able to be advanced at least 1 cm or more into the Canal. If the wire was left in place, the curved wires allowed for advancement into the Canal while the straight wires could only be advanced a short distance.

Example 2:

30 In another example, a surgical tool to provide for controlled punctures in the trabecular meshwork was created using Nitinol (nickel titanium alloy) wire, 0.004" (100 microns) diameter (Ft. Wayne Metals, Ft. Wayne, IN). The wire was formed with a 10 mm diameter coil bend for the distal 3 cm. The distal 2 mm of the tip was further formed with a small radius bend at approximately 90 degrees from the axis of the wire, directed toward the inside and remaining in the plane of the coil.

31 A microcannula was fabricated of a 3 cm long polyimide tube (Microlumen, Inc.), with an inner diameter of 140 microns and an outer diameter of 200 microns, adhesively bonded to a section of 26 gauge hypodermic tubing (Small Parts, Inc.). The hypodermic tubing was mounted in a short plastic sleeve for ease of manipulation. The polyimide tubing was heat set with a curvature of approximately 2.5 cm radius. A stainless steel guiding sheath was fabricated from sections of hypodermic tubing (Small Parts, Inc.) to create a stepped sheath with an inner diameter of approximately 300 microns. The guiding sheath was cut to 10 mm long and then mounted in a plastic shaft. The guiding sheath was mounted at the distal end of the shaft and at a right angle to the shaft axis. This configuration of sheath allowed for the tip of the guiding sheath to be

directed at Schlemm's Canal by one hand, while the cannulation was performed by the other hand, giving better positioning control for the procedure.

32 An ex-vivo human eye was placed in a holding cup and positioned under a stereomicroscope. A rectangular flap was cut approximately 4 mm on a side at the limbus. The flap was excised to approximately ½ scleral thickness. The tissue bed was further dissected to reveal Schlemm's Canal, and the Canal was de-roofed to allow access. The microsurgical tool was loaded into the microcannula by advancing the tool proximal end into the cannula distal end and continuing until the proximal end could be grasped at the proximal end of the cannula. The tool was oriented so that the curvature of the coil bend was approximate to the curvature of Schlemm's Canal. The tool was then withdrawn into the cannula approximately 3 mm, and the tip of the microcannula was inserted into the proximal end of the guiding sheath. Under the microscope, the distal tip of the guiding sheath was placed at the ostium of Schlemm's Canal. The microcannula was advanced into the canal approximately 30 degrees. While holding the microcannula steady, the tool was advanced slowly until the distal tip extended beyond the cannula tip and pierced the trabecular meshwork. The distal tip of the tool could be observed through the cornea, entering the anterior chamber. The microcannula was withdrawn slightly, further tearing the trabecular meshwork. The tool was then withdrawn into the cannula and the system withdrawn from the Canal.

Example 3.

33 In another example, a signaling means for determining the location of the microcannula was fabricated. A single strand plastic optical fiber (POF) (Biogeneral, Inc.) 100 microns in diameter was used with a flat distal tip. The fiber was disposed within an instrument assembly comprising a polyimide microcannula 110 microns ID and 160 microns OD (MicroLumen, Inc.), which was bonded to a needle assembly. The needle assembly consisted of a base section of 18 gauge hypodermic tubing, with a 14 gauge tubing guide tube fabricated so as to slide forward and backward along the 18 gauge tube for a fixed distance of 15 mm. The distal tip of the guide tube was comprised of a 28 gauge tube to direct the microcannula and POF during insertion. The POF was illuminated using a battery powered red laser diode (Digikey Corp.) in a small plastic housing. A second POF was also fabricated with a distal tip cut at approximately 60° and the jacket lightly scraped off opposite the bevel. This provided a partially directed illumination spot.

34 An ex-vivo human eye was placed in a soft cup stage under a stereomicroscope. A surgical flap was created at the limbus and the flap removed to reveal Schlemm's Canal. The tip of the guide tube was placed at the os of the Canal. The microcannula and POF were advanced into the canal with the light source on. The illuminated tip of the fiber was seen through the scleral

tissues in the case of the flat tipped POF. Using the beveled POF, illumination could be viewed from within the anterior chamber of the eye depending on the rotation of the microcannula, allowing the appropriate surgical tissues such as the trabecular meshwork to be targeted.

Example 4.

In another example, Schlemm's Canal of an eye is cannulated with the microcannula described in example 3. The signaling beacon inner member is used to verify position of the tip of the microcannula in the desired location of the eye and with proper rotational alignment with respect to the TM. The signaling beacon inner member is removed and a surgical tool inner member to remove tissue from the TM is guided into the lumen of the microcannula and advanced to the distal tip. The inner member also incorporates suction to remove tissue debris. After removal of TM tissue, the surgical tool inner member is exchanged for the signal beacon inner member. The microcannula may be positioned to another area of Schlemm's canal to repeat the process as needed to reduce IOP to an appropriate level.

In summary, the invention may include:

A microcannula based microsurgical device designed to operate within a tissue tract of the eye and to remove a controlled amount of ocular tissue comprising,
a flexible tubular sheath with an outer diameter of 250 microns or less, with proximal and distal ends, to fit within the tissue tract;
a distal assembly for fluid tight introduction of materials and tools;
and an inner member with a proximal end and a distal tip,
with the sheath and inner member sized such that the inner member fits slidably within the sheath and may be removed separately from the sheath while in the tissue tract.

A microcannula based microsurgical device as described above, wherein the tissue tract is Schlemm's Canal of the eye.

A microcannula based microsurgical device as described above, wherein the tissue tract is created by the flexible tubular sheath and inner member.

A microcannula based microsurgical device as described above, wherein the tissues removed comprise the Trabecular Meshwork.

A microcannula based microsurgical device as described above, wherein the flexible tubular sheath comprises polyimide or fluoropolymer.

A microcannula based microsurgical device as described above, wherein the flexible tubular sheath is curved in the range of 10–15 mm diameter.

A microcannula based microsurgical device as described above, wherein the inner member comprises nickel titanium alloy.

A microcannula based microsurgical device as described above, wherein the inner member comprises tungsten.

A microcannula based microsurgical device as described above, wherein the inner member comprises an optical fiber.

A microcannula based microsurgical device as described above, wherein the optical fiber is illuminated with visible light.

A microcannula based microsurgical device as described above, wherein the optical fiber is illuminated with infrared light.

A microcannula based microsurgical device as described above, wherein fiber optic illumination is directed at an angle of 45 to 135 degrees from the axis of the microcannula, from the proximal end of the microcannula

A microcannula based microsurgical device as described above, wherein the inner member is curved in the range of 10–15 mm diameter.

A microcannula based microsurgical device as described above, further comprising a second inner member or tool to cut or ablate tissues that interchanges with the first inner member used to position the distal tip at a predetermined position.

A microcannula based microsurgical device as described above, wherein the outer member has a distal segment comprising a hole or series of holes disposed along the axis of the member.

A microcannula based microsurgical device as described above, wherein the outer member comprises a multi-lumen tube.

A microcannula based microsurgical device as described above, wherein the inner member has a distal tip that is shaped for tissue dissection or removal.

A microcannula based microsurgical device as described above, wherein suction is used to aid tissue dissection and removal.

A microcannula based microsurgical device as described above, wherein the distal tip advances and penetrates the trabecular meshwork from a 45 to 135 degree direction from the axis of the outer sheath.

A microcannula based microsurgical device as described above, wherein the outer sheath additionally comprises a plurality of markers set at regular intervals such that each marker is spaced from adjacent markers by a fixed distance along the sheath to provide depth measurement.

A microcannula based microsurgical device as described above, wherein, the outer sheath additionally comprises materials to enhance observation of the device positioning under image guidance.

While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.

Drawings:

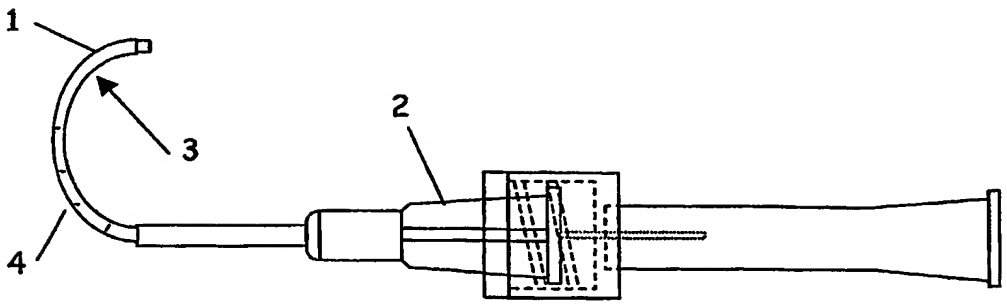

Fig. 1

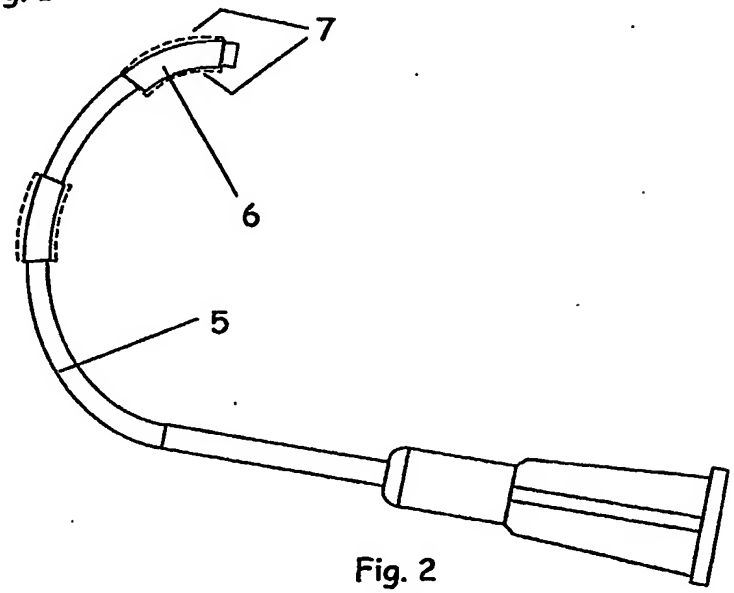

Fig. 2

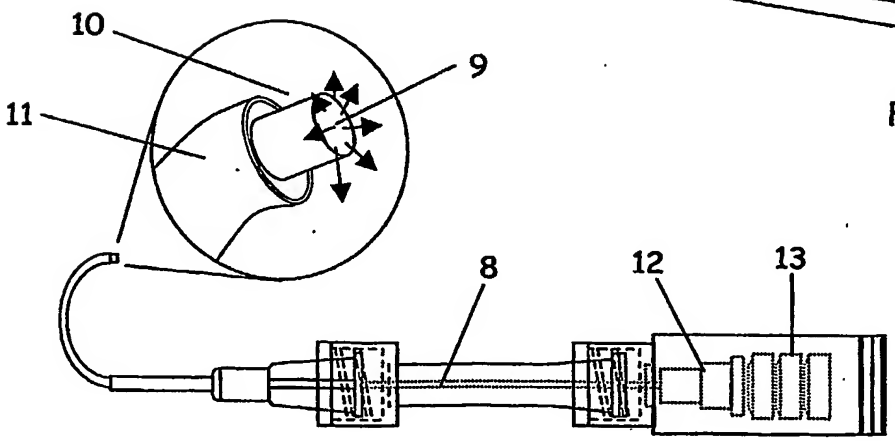

Fig. 3

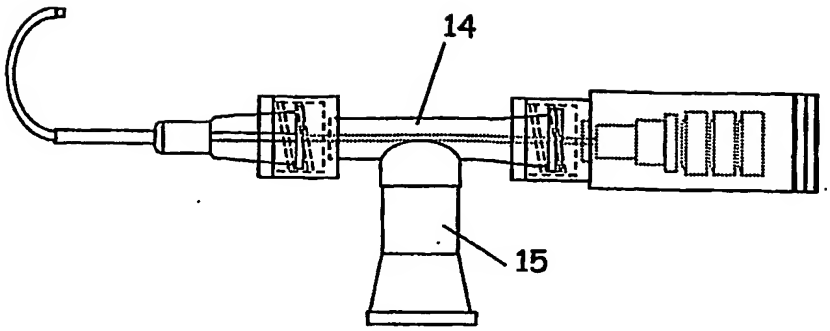

Fig. 4

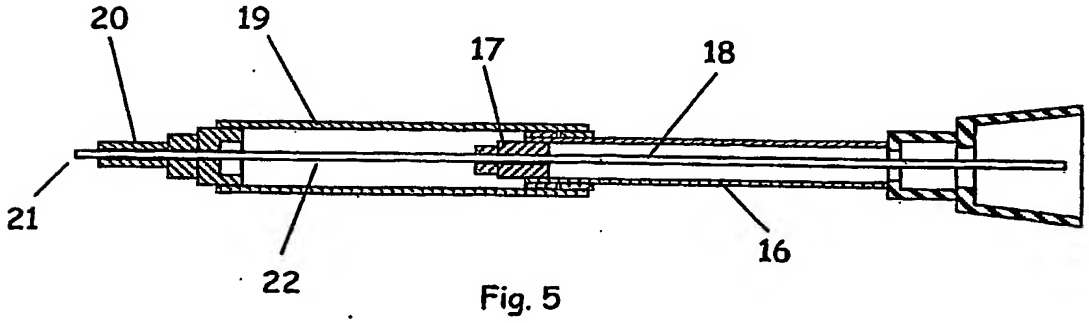

Fig. 5

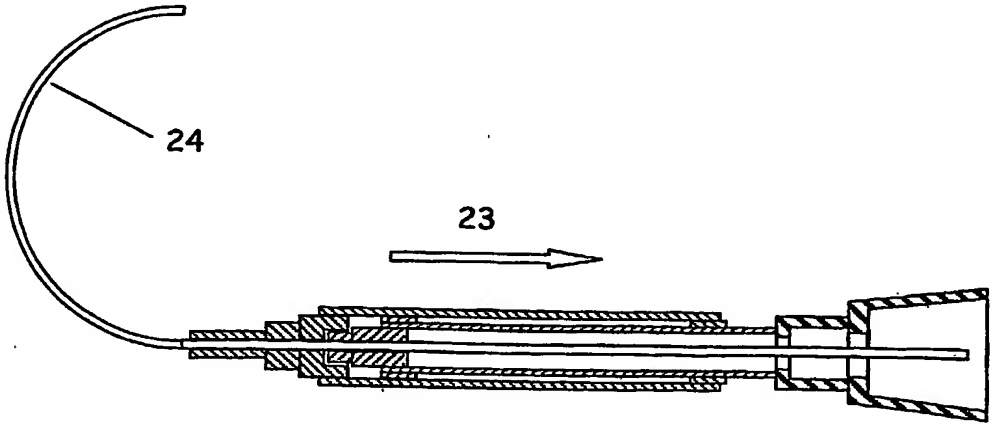

Fig. 6

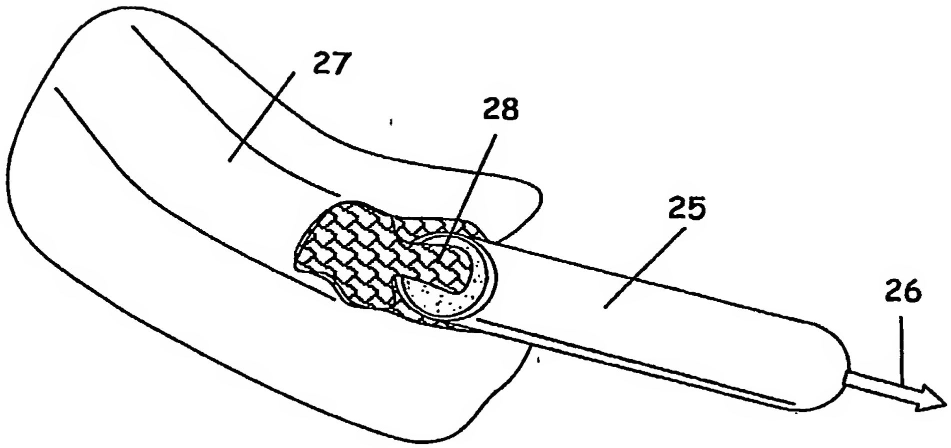

Fig. 7

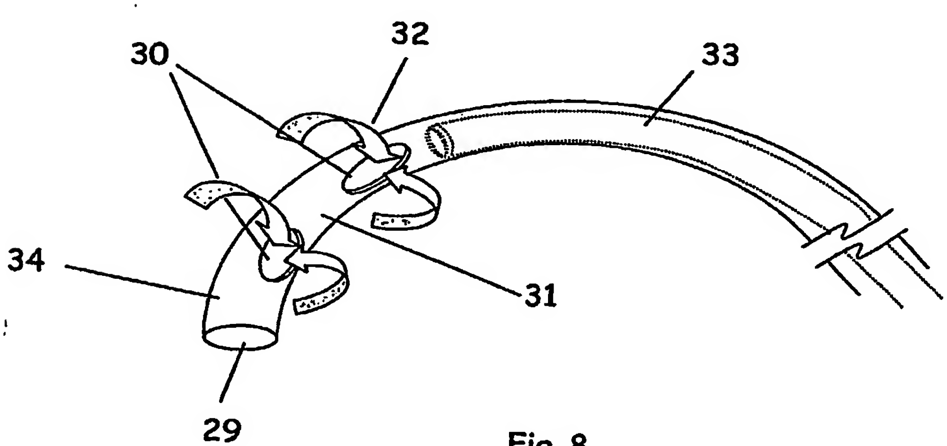

Fig. 8

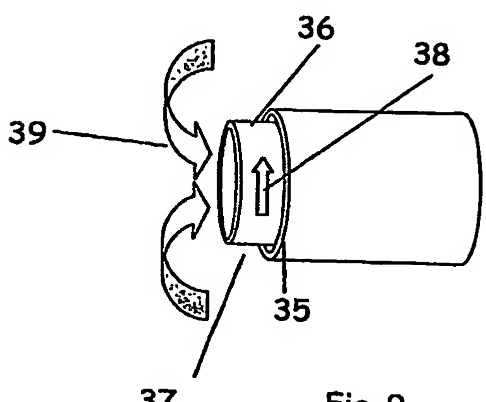

Fig. 9

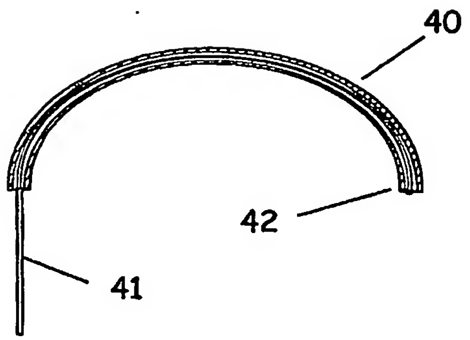

Fig. 10a

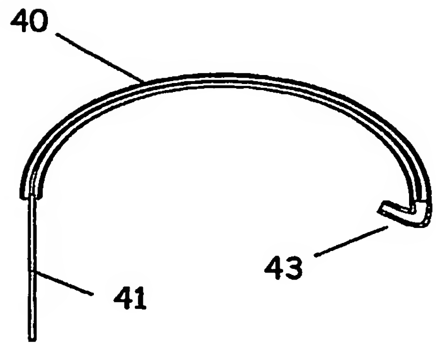

Fig. 10b

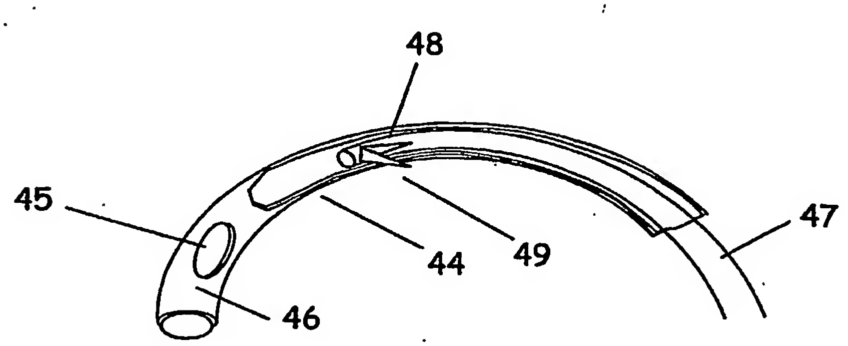

Fig. 11